

# DOWNSTREAM USE OF SPL

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# DailyMed Website

## National Library of Medicine (NLM)

DailyMed - Windows Internet Explorer provided by MSN & Bing


http://dailymed.nlm.nih.gov/dailymed/about.cfm

File Edit View Favorites Tools Help

Favorites Pin It InterLink - Login SPL-work-group - Downstre... FDA Label Search Structured Product Labeling...

DailyMed

Skip to content Skip to Drug Search



**Daily Med**  
Current Medication Information

DailyMed provides high quality information about marketed drugs.  
Drug labeling on this Web site is the most recent submitted to the Food and Drug Administration (FDA) and currently in use; it may include, for example, strengthened warnings undergoing FDA review or minor editorial changes. These labels have been reformatted to make them easier to read.

**Options**

- Home
- E-mail Label Information
- Downloads
- Archives
- Notify of Updates
- Contact Us
- Help
- Web Services

**Additional Resources**

- SPLIMAGE Specification Version 3.0.2
- Report Adverse Event
- SPL Format Previewer for Label Authors
- Product Identification System

At the present time this Web site does not contain a complete listing of labels for approved prescription drugs. Currently this Web site contains **42358** drugs.

Search :  **GO** [Advanced Search](#)

Limits: ☐ Drug Name ☐ NDC Code ☐ Drug Class ☐ Setid


Label Type: ☐ Human Drugs ☐ Animal Drugs


**About DailyMed**

DailyMed provides high quality information about marketed drugs. This information includes FDA labels (package inserts). This Web site provides health information providers and the public with a standard, comprehensive, up-to-date, look-up and download resource of medication content and labeling as found in medication package inserts. The National Library of Medicine (NLM) provides this as a public service and does not accept advertisements.

Drug labeling and other information in the SPL is what has been most recently submitted by drug companies to the Food and Drug Administration (FDA) as drug listing information (See 21 CFR part 207). The drug labeling has been reformatted to make it easier to read but its content has not been altered or verified by FDA or National Library of Medicine. The drug labeling on this Web site may not be the labeling on currently distributed products or identical to the labeling that is approved. Drugs marked "OTC monograph final" or "OTC monograph not final" are not checked for conformance to the monograph. Drugs marked "unapproved" on this Web site have not been reviewed by FDA for safety and efficacy and their labeling has not been approved. For more information about unapproved drugs, [visit Enforcement Activities by FDA](#).

Other information about drugs may also be available. NLM regularly processes data files uploaded from FDA's system and provides and maintains this Web site for the public to use in accessing the information. Additional information about medicines is available on NLM's MedlinePlus Web site <http://www.nlm.nih.gov/medlineplus/medicines.html>.

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Done

Internet 125%

# What is Downstream Use of SPL?

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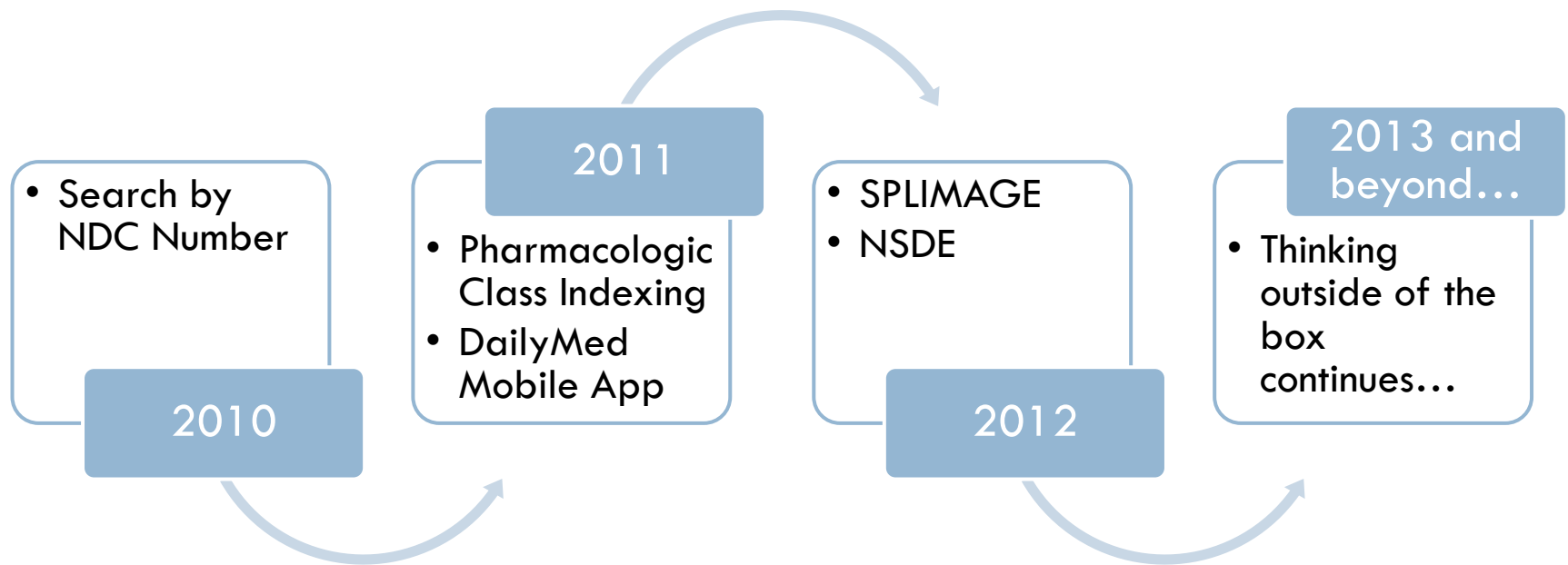
- Recognizing and exploring potential uses of SPL.
- Work to identify factors on how we can maximize the use of SPL within our industry as well as outside of the pharmaceutical industry.

# Current Downstream Uses of SPL

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- NDC Number
- Pharmacological Class Indexing
- Data Elements
- SPLIMAGE
- NSDE

# Downstream Use of SPL - Timeline





**SPLIMAGE**

# SPLIMAGE – Definition

- What is SPLIMAGE?
  - ▣ Collaboration with the FDA and NLM.
  - ▣ NLM studied imaging of oral solid dosage forms for prescription products.
  - ▣ Result is technical recommendations for a SPLIMAGE file composition and format.
- Who can use SPLIMAGE?
  - ▣ Oral solid dosage forms that are submitted to the FDA with SPL documents.

# SPLIMAGE – The Basics

- The SPLIMAGE is comprised of two or more views of the same dosage form of the product.
- This should represent front and back views of the dosage form.
- Any imprint and/or symbol should be clearly identifiable.
- Viewer should not be required to rotate the image in order to read it.
- Images that are submitted with SPL should be included in the same directory as the SPL file.

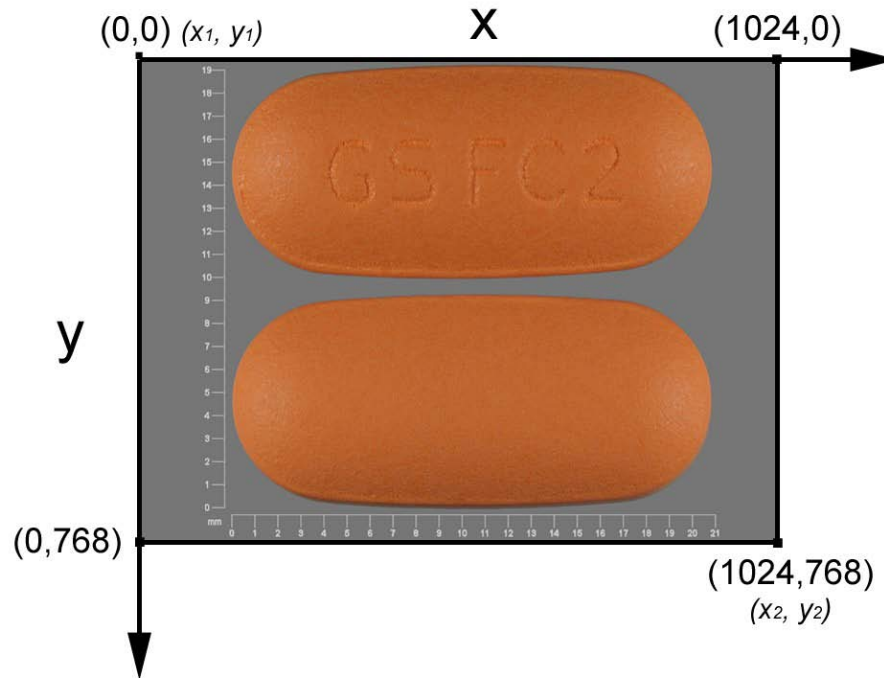


# SPLIMAGE – Technical Specifications

- Image should portray the visual characteristics that one can readily identify.
- Image size: 1024 pixels wide by 768 pixels high.
- The background a standard grey (RGB=118;118;118).
- Image coordinates are presented in standard (x,y) position where the origin position (0,0) is defined as being at the top left of the image.

# SPLIMAGE – Technical Specifications

And, here  
you  
thought  
that you  
would  
NEVER  
use  
algebra  
again!



*Image Area Defined by Coordinates =  $(0,0,1024,768)$   
 $(x_1, y_1, x_2, y_2)$*

# SPLIMAGE – Technical Specifications

- Image file size requirements:
  - ▣ JPEG format
  - ▣ File size limited to 150kB (kilobytes).
  
- Two possible arrangements:
  - ▣ Vertical Oral Solid Dosage Form Layout
  - ▣ Horizontal Oral Solid Dosage Form Layout

# SPLIMAGE – Product Image Layout

- What is Aspect Ratio?

Longest oral solid dosage form image axis

Shortest oral solid dosage form image axis

- Vertical Oral Solid Dosage Form Layout

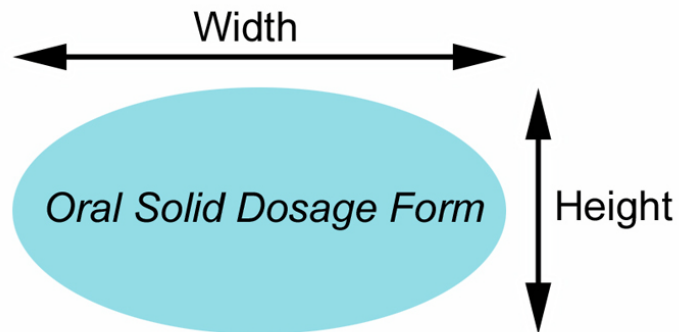
- ▣ Aspect ratio  $\geq 1.42$  mm.

- Horizontal Oral Solid Dosage Form Layout

- ▣ Aspect ratio  $< 1.42$  mm.

# SPLIMAGE – Product Image Layout

## Vertical Oral Solid Dosage Form

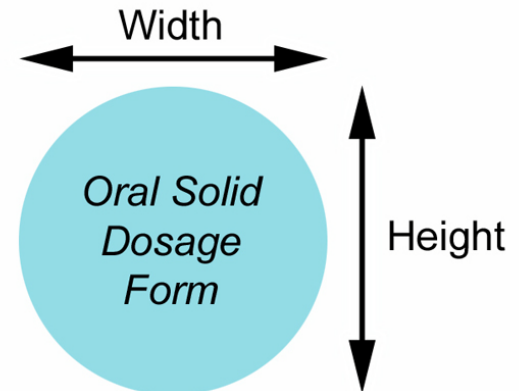


1 mm

Aspect Ratio = Width (8 mm) : Height (4 mm)  
= 8 mm : 4 mm  
= 2 : 1

2 > 1.42 therefore use Vertical Oral Solid Dosage Form Layout

## Horizontal Oral Solid Dosage Form



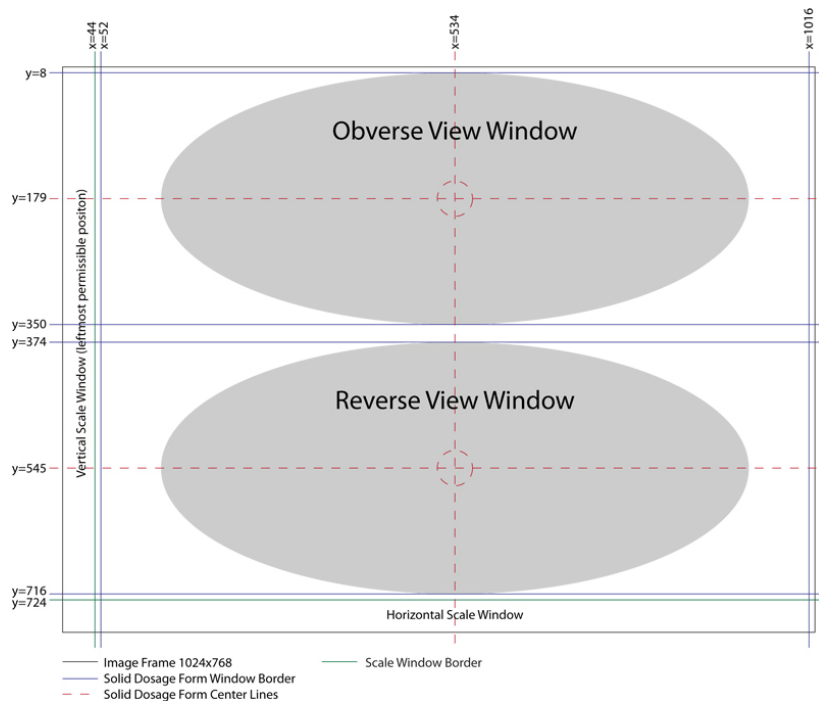
1 mm

Aspect Ratio = Width (5 mm) : Height (5 mm)  
= 5 mm : 5 mm  
= 1 : 1

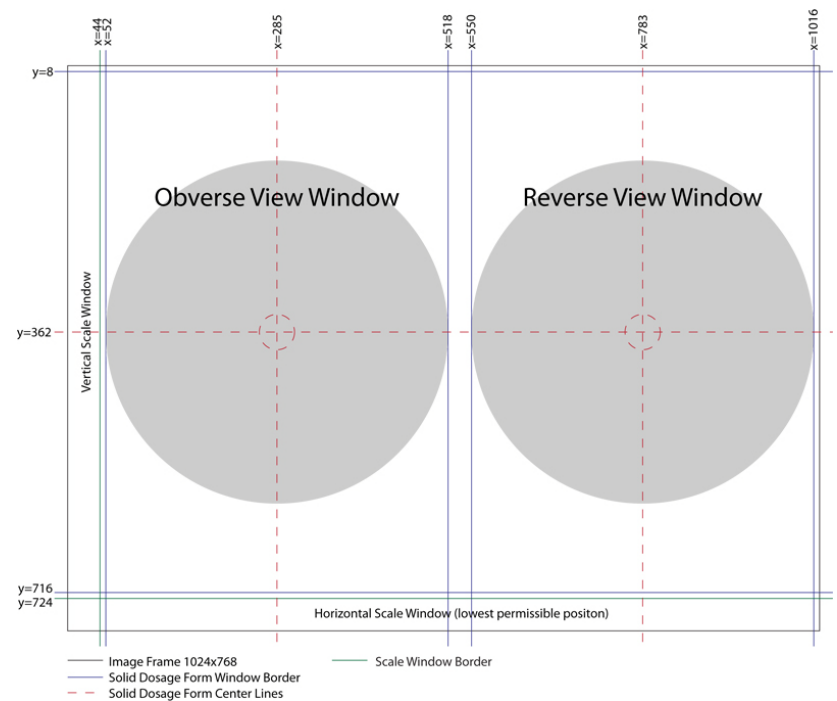
1 < 1.42 therefore use Horizontal Oral Solid Dosage Form Layout

# SPLIMAGE – Product Image Layout

## Vertical Oral Solid Dosage Form



## Horizontal Oral Solid Dosage Form



# SPLIMAGE – Product Image Layout

## Vertical Oral Solid Dosage Form

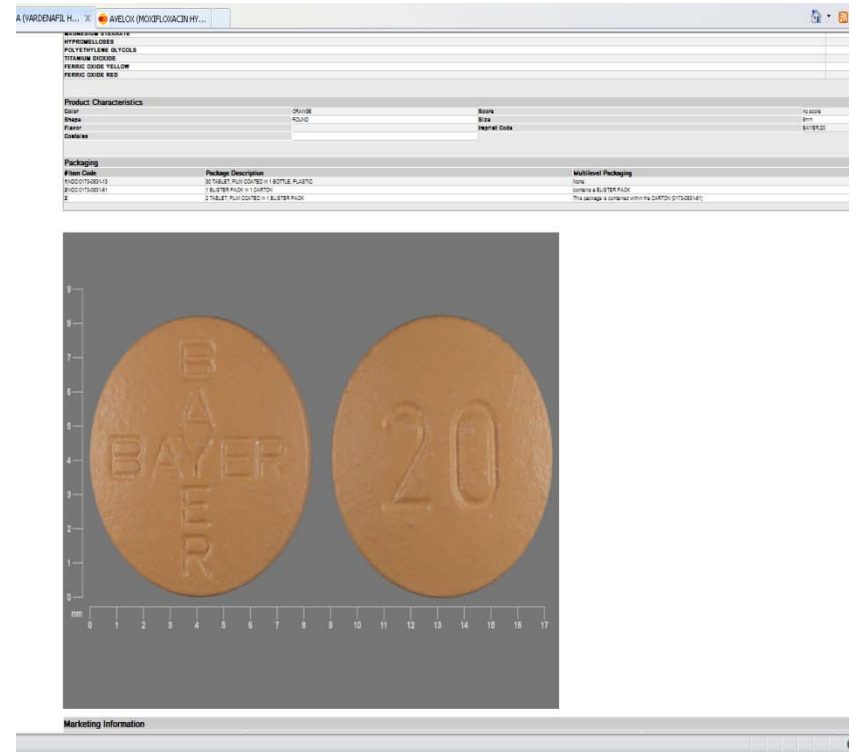


## Horizontal Oral Solid Dosage Form



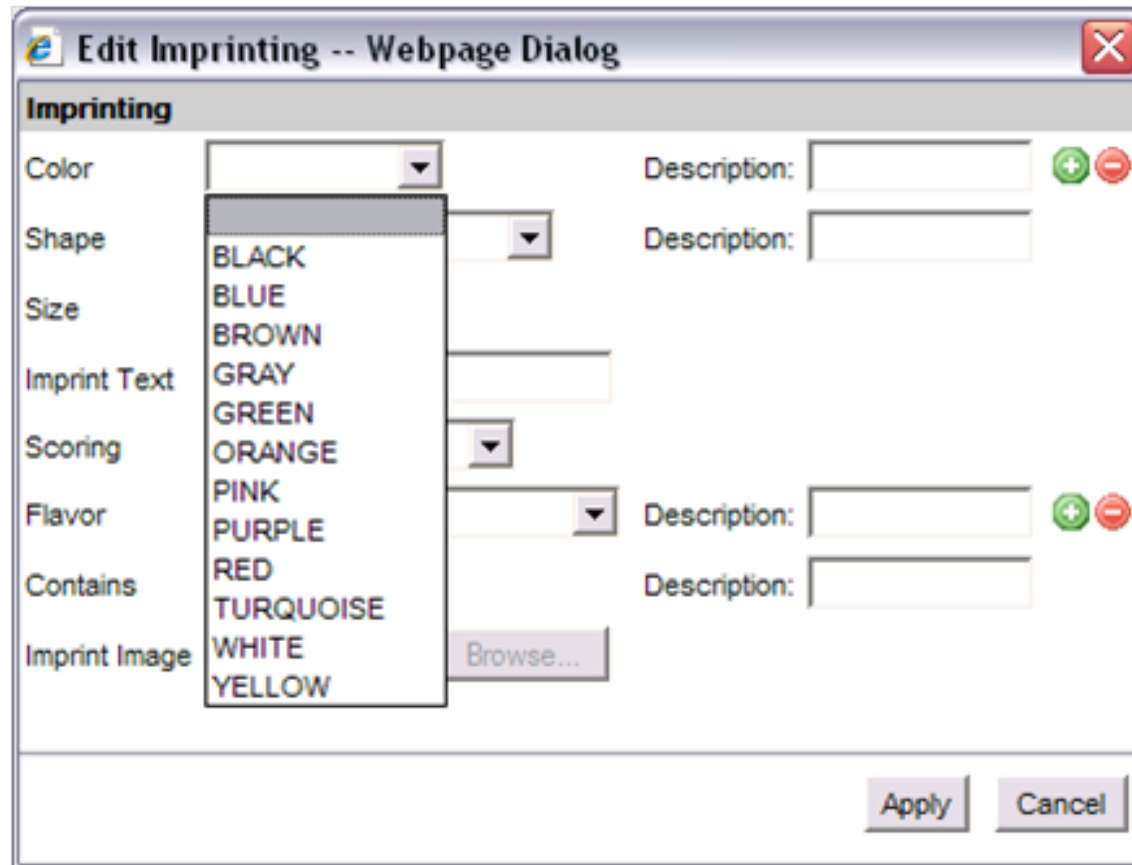
## Vertical Oral Solid Dosage Form

### Example: Avelox





# SPLIMAGE – Benefits (Pill Color)



The screenshot shows a web-based dialog box titled "Edit Imprinting -- Webpage Dialog". The "Imprinting" section is active, displaying various settings for a pill imprint. A dropdown menu for "Color" is open, listing 12 color options: BLACK, BLUE, BROWN, GRAY, GREEN, ORANGE, PINK, PURPLE, RED, TURQUOISE, WHITE, and YELLOW. The "Description:" field for the selected color is empty. Other fields include "Shape", "Size", "Imprint Text", "Scoring", "Flavor", and "Contains", each with a corresponding description field. The "Imprint Image" field has a "Browse..." button. The dialog box has "Apply" and "Cancel" buttons at the bottom right.

Property	Value	Description
Color	[Dropdown Menu Open]	[Empty]
Shape	[Dropdown]	[Empty]
Size	[Empty]	[Empty]
Imprint Text	[Empty]	[Empty]
Scoring	[Dropdown]	[Empty]
Flavor	[Dropdown]	[Empty]
Contains	[Empty]	[Empty]
Imprint Image	[Browse...]	[Empty]

# SPLIMAGE – Benefits (Pill Color)

- **Why do the colors/shapes I select sometimes not match the pills?**
  - ▣ When color and shape values are entered into the drug label, every effort is made to best match the sample to the selected value.
  - ▣ Subjective decision and thus can create what appear to be inconsistent results when viewing large numbers of pills.

# **SPLIMAGE – Further Downstream Use?**

- ☐ **Standardize the color and shape values?**
- ☐ **Searching on multiple colors on the same pill?**

# SPLIMAGE – Specifications Summary

<b>Image Size, Overall Composition &amp; File Name</b>	<ul style="list-style-type: none"><li>• 1024 pixels wide x 768 pixels high (XGA size standard).</li><li>• 24-bit truecolor image, sRGB colorspace.</li><li>• Two composition layout options based on the aspect ratio (AR) of the particular oral solid dosage form image sample:<ul style="list-style-type: none"><li>i. Vertical Oral Solid Dosage Form Image Layout [AR <math>\geq</math> 1.42]</li><li>ii. Horizontal Oral Solid Dosage Form Image Layout [AR &lt; 1.42]</li></ul></li><li>• Oral solid dosage form images should be segmented from the macro imaging background used, must have clean outlines, and must be placed against a medium gray (24-bit RGB value of 118,118,118) background.</li><li>• Preservation of proper scaling to oral solid dosage forms such that the final SPLIMAGE preserves the original product aspect ratio.</li><li>• Horizontal &amp; vertical millimeter scales to accurately reflect the size of the oral solid dosage form.</li></ul>
<b>Image File Type &amp; Compression</b>	<ul style="list-style-type: none"><li>• JPEG Compression (ISO/IEC 10918).</li><li>• JPEG compression should be set to the highest quality offered by the creation software which will allow the SPLIMAGE file to be equal to or smaller than a 150kB file size limit.</li><li>• Maximum image file size is: 150kB</li></ul>
<b>Image File Submission Instructions, Technical Assistance &amp; SPLIMAGE Specification Feedback Instructions</b>	<p>For information regarding submission of images to the FDA as part of a product SPL, please refer to the following website:</p> <p><a href="http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm">http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm</a></p>

# SPLIMAGE – Need Help?

## □ Submission Instructions:

- <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

## □ Technical Support:

- SPLIMAGE file specification:  
[splimage@nlm.nih.gov](mailto:splimage@nlm.nih.gov)
- SPLIMAGE in SPL: [spl@fda.hhs.gov](mailto:spl@fda.hhs.gov)



# NDC SPL Data Elements File

# NSDE - NDC SPL Data Elements File

- Effective September 1, 2012
- Affects Part D Plan Sponsors
- FDA's Comprehensive NSDE file to edit PDEs (Prescription Drug Event).

# NSDE - NDC SPL Data Elements File

- Generated from SPL documents sent to FDA for inclusion in the FDA Online Label Repository at <http://www.labels.fda.gov>
- Comprehensive NSDE zip file available at: <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm240580.htm>



# Example: Comprehensive NSDE File

Item Code	NDC11*	Proprietary Name	Dosage Form	Marketing Category	Application Number or Citation	Product Type	Marketing Start Date	Marketing End Date
0007-4407-01	7440701	ARGATROBAN	INJECTION, SOLUTION	NDA	NDA 020883	HUMAN PRESCRIPTION DRUG	20001128	

\* **NDC11:** The NDC11 is a transformed version of the segmented NDC code using the algorithm defined by the National Council for Prescription Drug Programs (NCPDP).

# NSDE - NDC SPL Data Elements File

- CMS uses drug compendia's to edit NDCs on PDEs.
- If the NDC is not found on First Databank and/or MediSpan files, the PDE is rejected with code 735.
- Moving forward, now products will be rejected with code 54 and reject message will be "NDC not FDA listed."

# NSDE – Timing Issues

- An NDC listed on the NSDE file as of the 15th of each month will be used for PDE editing starting the 1st of the following month.
  - ▣ A new drug product (NDC) enters the market on September 19, 2012.
  - ▣ The NDC first appears on the November 1, 2012, NSDE file.
  - ▣ CMS editing file will implement the NDC on November 1, 2012.
  - ▣ CMS will reject PDEs for this NDC up to November 1, 2012.
  - ▣ PDEs for this NDC, regardless of date of service, should be resubmitted on or after November 1, 2012.

# NSDE – Benefits

- Each compendia has own terminology.
- SPL Labeling allow importation of coded data
- Result: More rapid incorporation of data
  - ▣ For new products or
  - ▣ For product updates
- Consistent application of data
- Easier use for all sponsors

# Downstream Use of SPL – Future Possibilities...

- Barcode scan on hand-held devices
  - Serialization
  - Public Safety
  - Streamline information available on the DailyMed to make it user friendly.
- 
- **The possibilities are truly endless...**

# In Conclusion....

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- **Drug Companies:** Faster dissemination of drug product information
- **Medical Professionals:** Better prescribing decisions
- **Health Care Payers:** Reduced costs
- **Patients:** Educated & informed about adverse event

# Questions?



**Join Downstream Use of SPL  
Discussion:**

[http://spl-work-  
group.wikispaces.com/Downstream  
+Uses+of+SPL](http://spl-work-group.wikispaces.com/Downstream+Uses+of+SPL)